TESTIMONY OF
DR. DANIEL ENGELJOHN
DEPUTY ASSISTANT ADMINISTRATOR
OFFICE OF POLICY, PROGRAM, AND EMPLOYEE DEVELOPMENT
FOOD SAFETY AND INSPECTION SERVICE
BEFORE THE
U.S. HOUSE OF REPRESENTATIVES
COMMITTEE ON ENERGY AND COMMERCE

November 13, 2007

Mr. Chairman and members of the Committee, thank you for inviting me to appear before you today to discuss carbon monoxide (CO) in meat packaging. I am Dr. Dan Engeljohn of USDA's Food Safety and Inspection Service (FSIS).

FSIS is the USDA public health regulatory agency responsible for the administration of laws and regulations that are designed to ensure that the nation's commercial supply of meat, poultry, and egg products is safe, wholesome, and properly labeled, regardless of whether those products are sold in the United States or imported to, or exported from, the United States. FSIS is also responsible for determining that foreign meat and poultry plants operate under an inspection system equivalent to the United States before they can export to the United States.

.

Reviewing Technology in the Meat Industry

The development of new technologies is largely initiated by industry itself, as it responds to consumer demands. There are two different types of technologies that are

subject to review: processing technologies and ingredient technologies. Processing technologies are those technologies developed to aid in the production of meat, poultry, and egg products. Examples of processing technologies include carcass washes, the steam vacuum, and steam pasteurization.

Ingredient technologies are those technologies that involve the addition of an ingredient, generally as defined by FDA, to a product or the use of packaging to ensure safety or increase shelf life. Examples of this kind of technology include carbon monoxide packaging and irradiation.

Prior to 2000, the review process for new ingredients was lengthy and cumbersome. FDA was responsible for the initial safety review. This was then followed by a review by FSIS to determine the acceptability or suitability of the technology; that is, to determine whether the ingredient served the purpose for which it was intended. In 2000, FSIS and FDA entered into a Memorandum of Understanding allowing simultaneous review of new technologies to increase the speed with which useful new food ingredients could be used.

FDA determines the safety of a food ingredient and its safe levels of use, while simultaneously FSIS evaluates whether the ingredient has its intended technical effect. Allowing these evaluations to occur at the same time effectively decreases the time any food ingredient spends in review.

Under the Federal Meat Inspection Act (FMIA), FSIS is responsible for determining the efficacy and suitability of food ingredients and additives in meat products as well as prescribing safe conditions of use. Suitability refers to the effectiveness of the ingredient or additive in performing the intended purpose of use and the assurance that the conditions of use will not result in an adulterated product or one that will mislead consumers.

Carbon Monoxide in Meat Packaging

One form of technology used by the meat industry that has received a great deal of attention in recent months is carbon monoxide in packaging. Carbon monoxide is used to stabilize the color pigment of meat, when it is red and, therefore, most appealing to consumers. Use of carbon monoxide in packaging does not impart a color to the meat; it simply maintains its naturally occurring color.

Carbon monoxide does not become a part of the product and dissipates as soon as the package is opened. This is unlike other ingredients used to stabilize the red color of meat, such as citric acid, sodium ascorbate, and rosemary extract, all of which actually do become a part of the product and may have a lasting effect on product color even after packaging is removed.

In 2002, carbon monoxide, for use as a component of modified atmosphere packaging, was accepted by FDA as being “Generally Recognized as Safe,” or GRAS.

GRAS refers to a chemical or substance that is added to food and is exempt from regulation because its extensive use has produced no known harmful effects. GRAS notifications must be accompanied by scientific data establishing that, under the proposed conditions of use, the substance is safe, and that it will be used at the lowest levels necessary to accomplish the intended functional effects. USDA assesses suitability of use under the proposed conditions after FDA has assessed the ingredient's safety.

In accordance with our Memorandum of Understanding with FDA, USDA in 2004 reviewed the GRAS notice submitted by Precept Foods, and wrote two letters to FDA, dated April 28 and June 2, 2004 in response.

It is common for FSIS to find data in original GRAS Notices to be insufficient for a suitability determination and for us to notify FDA that we consider the petition to be incomplete. The petitioners then provide additional data which may result in our accepting the suitability of the ingredient or substance with or without specific use conditions.

On April 28, 2004, we sent FDA a letter that reflected a preliminary FSIS decision that was based on the data that were submitted with the original GRAS Notice from Precept Foods, LLC, the petitioner. As a result of the April 28 letter, the petitioner submitted additional data to address our concern that the application of carbon monoxide may be misleading to consumers if used as described in the initial GRAS notice.

The June 2, 2004 letter describes that our earlier concerns had been addressed by Precept Foods, LLC. Precept provided data evaluating shelf life, microbial outgrowth, and color of meat products treated and packaged using various methods including that proposed in the original GRAS notice. These data are generally described in the third paragraph of the June 2 letter.

As stated in the June response, Precept provided additional information to FSIS addressing specific suitability concerns raised in the April 28 letter. Based on the spoilage information and use conditions provided by Precept, FSIS reversed its decision and determined that the use of carbon monoxide is suitable in modified atmosphere packaging, but only when a use-by or freeze-by date is applied. Use-by or freeze-by dates are required on all systems in which carbon monoxide is in direct contact with the meat.

In November 2005, FDA received a petition asking it to withdraw its decision that carbon monoxide in meat packaging is Generally Recognized as Safe. FSIS will continue to make its labeling decisions and its suitability reviews on the basis of FDA's safety conclusions. Based on the data presented at the time, FSIS stands by its 2004 decision on the suitability of the use of carbon monoxide in meat packaging. However, as always, FSIS would reassess the situation if new data becomes available. FSIS has also asked USDA's Agricultural Research Service (ARS) to conduct research related to packaging systems.

Conclusion

Thank you for the opportunity to testify before you today. I look forward to addressing any questions you might have.